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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/836,704 | 04/16/2001 | Sam L. Woo | 9584-027-999 | 6599 |

20583 7590 01/17/2003

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| EXAMINER |
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RILEY, JEZIA

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| ART UNIT | PAPER NUMBER |
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1637

DATE MAILED: 01/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|-----------------------------|-----------------|--------------|
| Offic Action Summary | Application No. | Applicant(s) |
| | 09/836,704 | WOO ET AL. |
| Examiner | Art Unit | |
| Jezia Riley | 1637 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM

THE MAILING DATE OF THIS COMMUNICATION.

Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed

- after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If the period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 26 November 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-60 is/are pending in the application.

4a) Of the above claim(s) 29-52 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-28 and 53-60 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) 1-60 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .

4) Interview Summary (PTO-413) Paper No(s). _____ .

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____ .

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-28 and 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 54 are vague and indefinite because in formula III if R3 is the of formula as shown in line 30 and X is oxygen then the bond linking R3 in formula III will be and O-O bond which is unstable.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-7, 11, 13-28 and 53-60 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Grossman et al. (5,470,705) in view of Stratagene Catalog p. 39, 1988.

Grossman et al. discloses a method of detecting one or more of a plurality of different sequences in a target polynucleotide. In practicing the method, there is added to the target polynucleotide, a plurality of sequence-specific probes, each characterized by (a) a binding polymer having a probe-specific sequence of subunits designed for base-specific binding of the polymer to one of the target sequences, under selected binding conditions. The polymer chain may be a substantially uncharged, water-soluble chain, such as a chain composed of polyethylene oxide (PEO) units or a polypeptide chain, where the chains attached to different-sequence binding polymers have different numbers of polymer units.

Methods of preparing polymer chains in the probes generally follow known polymer subunit synthesis methods. Methods of forming selected-length PEO chains are discussed, and detailed in Examples 1-4. These methods, which involve coupling of defined-size, multi-subunit polymer units to one another, either directly or through charged or uncharged linking groups, are generally applicable to a wide variety of polymers, such as polyethylene oxide. The methods of polymer unit coupling are suitable for synthesizing selected-length copolymers, e.g., copolymers of polyethylene oxide units alternating with polypropylene units.

FIG. 2 illustrates one method for preparing PEO chains having a selected number of HEO units. As shown in the figure, HEO is protected at one end with dimethoxytrityl (DMT), and activated at its other end with methane sulfonate. The activated HEO can then react with a second DMT-protected HEO group to form a DMT-protected HEO dimer. This unit-addition is carried out successively until a desired PEO chain length is achieved. Details of the method are given in Example 1. Coupling of the polymer chains to an oligonucleotide can be carried out by an extension of conventional phosphoramidite oligonucleotide synthesis methods, or by other standard coupling methods. FIG. 4A illustrates the coupling of a PEO polymer chain to the 5' end of an oligonucleotide formed on a solid support, via phosphoramidite coupling. Details are given in Examples 3B and 3C. (See columns 2-21 and Figures 1-15).

6. Claims 1-7, 11, 13-28 and 53-60 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Grossman (6395486) in view of Stratagene Catalog p. 39, 1988.

Grossman discloses compositions and methods for the analysis of multiple nucleic acid target sequences. The compositions comprise a probe comprising a target-specific portion for sequence-specific hybridization to a target nucleic acid sequence, and a tag; and a mobility-modifier comprising a tail and a tag complement for binding to the tag. The associated methods generally comprise the steps of providing a sample potentially containing one or more target nucleic acid sequences; providing one or more probes, each probe comprising a target-specific portion and a tag; providing one or

more mobility modifiers, each mobility modifier comprising a tag complement and a tail; contacting the probe(s) and the target nucleic acid sequence(s) under conditions effective for sequence-dependent hybridization of the probe(s) and the target nucleic acid sequence(s); contacting the probe(s) and the mobility-modifier(s) under conditions suitable for selectively binding the probe(s) to the mobility modifier(s), thereby forming one or more a probe/mobility modifier complex(s); and analyzing the probe/mobility modifier complex(s) using a mobility-dependent analysis technique.

The mobility modifier 50 of the binary composition comprises a tag complement 55 portion for binding to the tag portion 15 of the probe, and a tail 60 for effecting a particular mobility in a mobility-dependent analysis technique. The tail portion of a mobility modifier may be any entity capable of effecting a particular mobility of a probe/mobility-modifier complex 80 in a mobility-dependent analysis technique. Preferably, the tail portion 60 of the mobility modifier 50 of the invention should have a low polydispersity in order to effect a well-defined and easily resolved mobility. In a particularly preferred embodiment, the tail portion of the mobility modifier comprises a polymer. Specifically, the polymer forming the tail may be homopolymer, random copolymer, or block copolymer. In one preferred embodiment, the polymer is polyethylene oxide (PEO), e.g., formed from one or more hexaethylene oxide (HEO) units, where the HEO units are joined end-to-end to form an unbroken chain of ethylene oxide subunits. Coupling of the polymer tails to a polynucleotide tag complement can be carried out by an extension of conventional phosphoramidite polynucleotide synthesis methods, or by other standard coupling methods, e.g., a bis-urethane tolyl-

linked polymer chain may be linked to an polynucleotide on a solid support via a phosphoramidite coupling. Alternatively, the polymer chain can be built up on a polynucleotide (or other tag portion) by stepwise addition of polymer-chain units to the polynucleotide, e.g., using standard solid-phase polymer synthesis methods.

7. Claims have added functions which the prior art has not analyzed such as for example the molecular weight or the attachment to the 3' or 5' end; but given the above 102 rejection analysis substantiating the basic characterization of the composition of the invention being the same as the reference, these added characteristics are presumed to be inherent in the prior art composition.

As it is pointed in *In re Fitzgerald* (205 USPQ), page 594, 2nd col., 1st full paragraph, supports the shifting of the burden of proof to the applicant that the instantly claimed invention is novel and unobvious over the prior art. Since both the prior art and the instant application prepare and use composition which appeared to be identical. The prior art therefore suggests the instant application under 35 U.S.C. § 103(a).

8. Stratagene shows gene characterization kits providing a variety of different reagents. Each kit provides a variety of different reagents which have been assembled and premixed specifically for a defined set of experiments.

10. Thus, it would have been obvious to someone of ordinary skill in the art, at the time the invention was made to prepare a kit comprising derivatives cited in Grossman

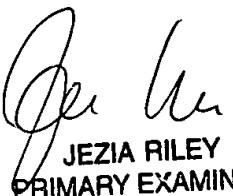
Art Unit: 1637

references. One would have been motivated to perform this kit as suggested by Stratagene, because it saves money and resources by reducing waste reagents since each of these reagents is needed in only microgram amounts when beginning a series of experiments, thus reducing the accumulation of unused chemicals (see lines 12-27 Stratagene catalog p.39).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 703-305-6855. The examiner can normally be reached on 9:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



JEZIA RILEY
PRIMARY EXAMINER

January 15, 2003